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EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/031,851	RAPP ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 10/17/2007. Claim(s) 20 has been cancelled. Claim(s) 1-19 are pending and examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified or repeated below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-13, and 17 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Wakeman (US Patent 3,317,540) in view of Berger (US Patent 4,574,084).

Wakeman discloses that arylsulfonamides and its known derivatives of formula I (col. 1, lines 15-39) are antimicrobial compounds in pharmaceutical compositions (col. 3, lines 3-20). By topical administration to skin broadly and hair, these pharmaceutical compositions can treat skin diseases because of their antiseptic, antidandruff, and disinfectant properties (col. 3, lines 53-56). Wakeman discloses the pharmaceutical compositions of tosylchloramide(s) and their alkali metal salts in a form, a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion (col. 2, line 32 to col. 3, line 38). Examples 4 and 5 disclose, chloramine-T, in an amount of 10% aqueous stock solution.

However, Wakeman does not expressly disclose the employment of tosylchloramide(s) in the methods of the particular skin diseases herein.

Berger discloses the general teaching that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi. Furthermore, these skin diseases can be effectively treated with biocidal compositions that are used for disinfection (col. 7, line 61 to col. 8, line 8).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes.

One having ordinary skill in the art at the time the invention was made would

have been motivated to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes because: (1) Wakeman teach antimicrobial, disinfectant, and biocidal pharmaceutical compositions comprising tosylchloramide(s) and their salts for treating skin diseases; (2) Berger teaches that common skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi; and (3) Berger also give the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating skin diseases such as psoriasis and herpes with an antimicrobial composition comprising tosylchloramide(s) as disclosed by Wakeman because of the beneficial therapeutic effects of tosylchloramide(s) on killing and destroying harmful microorganisms that cause such skin diseases.

Response to Arguments

Applicant argues that Wakeman is not directed to a pharmaceutical composition that can treat skin diseases. This is not persuasive because while Wakeman does not specifically teach skin diseases, Wakeman does clearly teach administration to the skin with an antimicrobial composition. The secondary reference, Berger, teaches common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi, which can be effectively treated with biocidal compositions that are used for disinfection.

In response to applicant's arguments against the references, one cannot show nonobviousness by attacking references individually where the rejections are based on

the combination of references. See *In re Keller*, 642 F. 2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues against the Berger reference because the mechanism of biocide activity of the disclosed composition comprising a chlorite solution and a peroxy compound is different than the tosylchloramides employed in the instant invention. This is not persuasive because the Berger reference was merely used to disclose the general teaching that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi, which can be effectively treated with biocidal compositions that are used for disinfection. Examiner notes that the rejection recites nothing about using the pharmaceutical composition of Berger.

Applicant argues that the compound in claim 1 is structurally distinct from that of Wakeman as shown in Applicant's response (pg. 4-5). This is not persuasive because claim 1 as written recites only "tosylchloramide." Applicant is requested to show where exactly the structure that was pointed out in Applicant's response (pg. 5) is in the instant claim set.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant finally argues against obviousness by raising concerns with regard to compatibility with skin and side effects. This is not persuasive because the cited prior

art references clearly disclose the compositions with pharmaceutical use with no mention of compatibility or side effects issues that would preclude enablement of the invention. Furthermore, Applicant is reminded that the standard for obviousness is not absolute but a reasonable expectation of success.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandevelde et al. (WO 91/07876) in view of Berger (US Patent 4,574,084).

Vandevelde et al. discloses that tosylchloramide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-8 and claims 1-28). Vandevelde et al. discloses the pharmaceutical compositions of tosylchloramide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-13 at page 9-20).

Vandevelde et al. does not expressly disclose the employment of tosylchloramide(s), in methods of the particular skin diseases herein.

Berger teach as discussed above.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes.

One having ordinary skill in the art at the time the invention was made would

have been motivated to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes because: (1) Vandevelde et al. teach an antimicrobial pharmaceutical composition comprising tosylchloramide(s) and their salts for treating skin diseases; (2) Berger teaches that common skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi; and (3) Berger also give the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating skin diseases such as psoriasis and herpes with an antimicrobial composition comprising tosylchloramide(s) as disclosed by Vandevelde et al. because of the beneficial therapeutic effects of tosylchloramide(s) on killing and destroying harmful microorganisms that cause such skin diseases.

Response to Arguments

Applicant argues that Vandevelde is not concerned with skin diseases, but rather treating the HIV virus. This is not persuasive because although Vandevelde teaches treatment against viruses, the Berger reference teaches that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi, which can be effectively treated with biocidal compositions that are used for disinfection.

Claims 1-19 are rejected under 35 U.S.C. 103(a) a: being unpatentable over Harwardt et al. (DE 41 37 544) in view of Berger (US Patent 4,574,084).

Harwardt et al. discloses that tosylchloramide(s) and its known derivatives, in

particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-4 and claims 1-7). Harwardt et al. discloses the pharmaceutical compositions of tosylchloramide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-5 at page 3-4).

Harwardt et al. does not expressly disclose the employment of tosylchloramide(s) in methods of the particular skin diseases herein.

Berger teach as discussed above.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloramide(s) and their salts in treating particular skin diseases such as psoriasis and herpes because: (1) Harwardt et al. teach an antimicrobial pharmaceutical composition comprising tosylchloramide(s) and their salts for treating skin diseases; (2) Berger teaches that common skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi; and (3) Berger also give the general teaching that such skin diseases can be treated with biocidal compositions that are used for disinfection. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating skin diseases such as

psoriasis and herpes with an antimicrobial composition comprising tosylchloramide(s) as disclosed by Harwardt et al. because of the beneficial therapeutic effects of tosylchloramide(s) on killing and destroying harmful microorganisms that cause such skin diseases.

Response to Arguments

Applicant argues that Harwardt is directed to oxidative disinfection agents that contain oxygen cleaving compounds, which are totally different from use of the tosylchloramide according to the instant invention. This is not persuasive because although the mechanism of action may differ, Harwardt clearly teaches treatment against viruses using Chloramin T, a tosylchloramide. The Berger reference teaches that common inflammatory skin diseases, such as psoriasis and herpes, are caused by bacteria, viruses, and fungi, which can be effectively treated with biocidal compositions that are used for disinfection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER